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APPLICATION NO. FILING		ILING DATE	DATE FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,388	09/27/2004		Jack Auzerie	0540-1025	
466	7590	03/16/2006		EXAMINER	
YOUNG &	tHOMI	PSON	EBRAHIM, NABILA G		
745 SOUTH 2ND FLOO		TREET	ART UNIT	PAPER NUMBER	
ARLINGTO		22202	1618		

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Applicati	on No.	Applicant(s)				
		10/509,3	88	AUZERIE, JACK				
	Office Action Summary	Examine	7	Art Unit				
		Nabila G.	Ebrahim	1618				
Period fo	The MAILING DATE of this commu r Reply	nication appears on th	e cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).								
Status								
1)	Responsive to communication(s) fil	ed on						
,	This action is FINAL . 2b)⊠ This action is non-final.							
3)□	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is							
·	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Dispositi	on of Claims							
4)🖂	· 4)⊠ Claim(s) <u>1-7</u> is/are pending in the application.							
•	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)	Claim(s) is/are allowed.							
6)⊠	Claim(s) <u>1-7</u> is/are rejected.							
7)	Claim(s) is/are objected to.							
8)□	Claim(s) are subject to restriction and/or election requirement.							
Applicati	on Papers							
9) The specification is objected to by the Examiner.								
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.								
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) 🔲	11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	ınder 35 U.S.C. § 119							
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:								
	1. Certified copies of the priority documents have been received.							
	2. Certified copies of the priority documents have been received in Application No							
	3.⊠ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).							
* 9	* See the attached detailed Office action for a list of the certified copies not received.							
Geo the attached detailed office action for a list of the continue copies not received.								
Attachment	t(s) e of References Cited (PTO-892)		4) Interview Summary	(PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)								
3) 🛛 Inforr	nation Disclosure Statement(s) (PTO-1449 o	r PTO/SB/08)	5) Notice of Informal P 6) Other:	atent Application (PTO-152)				
Paper No(s)/Mail Date <u>9/27/04</u> . 6) Other:								

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DETAILED ACTION

Receipt is acknowledged of the IDS filed 9/27/04.

Claim Rejections - 35 USC § 102

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 1. Claims 1-3, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al. US 4851392 (hereinafter "Shaw").

Shaw discloses a composition made of fiber or drug material, which is combined, with the hydrocolloid materials to form aggregates. Shaw uses different categories of drugs for his invention including, ion exchange resins such as colestyramine (col. 4, line 58), a buffer like sodium citrate and citric acid (col.7, line 61 bridging to col.8, line 1). The target pH adjustment is in a specified range of about 3.2 to about 4.7, this range overlaps with the given range in the instant application of 4-8. The composition can be made into pharmaceutical preparations like gels (col. 6, lines 64, and 65).

Note that the intended use of the claimed composition has not been given patentable weight, because the prior art compositions would be at least capable of performing said use.

Conclusion: claims 1-3, and 5-7 are anticipated by Shawn.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Krone et al. US 6036948 (hereinafter "Krone").

Krone discloses polyaspartamide derivatives as adsorbents for bile acids. For the "resins" being used as pharmaceuticals, colestyramine is used (col. 1,

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line 54-56), Krone also used natural amino acids like: L-alanine, L-leucine (col. 4, line 21), the instant application recites alanine and leucine, however, alanine and leucine encompasses the racemic forms of the two amino acids, which are L-and D- alanine and leucine. Krone uses also phosphate buffer (col. 6, line 30). *Conclusion:* claim 1 is anticipated by Krone.

Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al. US 4851392 in view of Castillo et al. WO 01/21209 (hereinafter "Castillo").

Shaw has been explained above.

Castillo teaches fatty acid/amino acid soaps, which comprise cationic exchange resins (page 5, lines 2, and 3), with buffers and pH-adjusting agents (page 7, lines 11, and 12), the pH is adjusted to 6.0 (example 2).

Accordingly, it would have been obvious to one skilled man in the art to advance the composition disclosed by Shaw and adjust the pH as Castillo teaches to about 6.0 since Castillo is disclosing an ophthalmic preparation, which is a topical preparation. The expected result would be a topical preparation containing colestyramine, a buffer and a pH regulator.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim 3/7/06

SUPERVISORY PATENT EXAMINER